JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
VOL. 66, NO. 22, 2015

ISSN 0735-1097/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jacc.2015.09.067

EDITORIAL COMMENT

When Transcatheter Therapy Moves to the "Forgotten Valve"*

Alec Vahanian, MD,†‡ Jean Michel Juliard, MD†‡

Tricuspid regurgitation (TR) is very frequent in the population. More than 80% of TR is secondary to left-sided heart disease that causes right ventricular (RV) volume or pressure overload. As an illustration, >20% of patients undergoing cardiac surgery for left-sided valvular disease present with significant TR (1,2).

Severe TR, either primary or secondary, is an independent predictor of poor prognosis. Both European and U.S. guidelines state that, in patients undergoing left-sided cardiac surgery, intervention on the tricuspid valve is indicated if TR is severe and should be considered in moderate TR with annular dilation and/or prior RV failure.

Early tricuspid surgery is at low risk. Conversely, when TR develops or persists after mitral valve surgery, reoperation carries a high risk related to cardiac and extracardiac conditions (1–3). Thus, there is a rationale for transcatheter treatment of the tricuspid valve. Today, we are at the very early phase of transcatheter tricuspid valve therapy in comparison with >200,000 transcatheter aortic valve replacements and >25,000 MitraClip implantations.

The initial experience of transcatheter therapy in patients with native TR was in compassionate use with the implantation of valve prostheses at the inferior and/or both superior vena cava. Self-expandable and balloon-expandable prostheses were used (4,5). These case reports show feasibility and clinical improvement ≥2 years with some RV remodeling. However, persistence of RV and atrial overload is a concern for long-term outcomes.

The first successful transcatheter tricuspid repair for severe TR was recently performed using the Mitralign system (Tewksbury, Massachusetts), which enables the performance of a plication of the tricuspid annulus reproducing the Kay operation (6,7). Ten patients have been treated to date. The TriCinch system (4Tech Cardio, Dublin, Ireland) comprises a corkscrew anchored in the tricuspid annulus, a self-expanding stent deployed in the inferior vena cava, and a Dacron band connecting both and tensioning the tricuspid annulus (8). To date, 8 patients have been enrolled in an ongoing feasibility trial.

SEE PAGE 2475

The MitraClip device (Abbott Vascular, Santa Clara, California) has been used anecdotally for the treatment of secondary TR. The study by Campelo-Parada et al. (9) in this issue of the *Journal* is original; the authors report a new concept that consists in the implantation of a Spacer, positioned at the level of the tricuspid orifice on a rail anchored in the RV apex. The aim is to reduce TR by decreasing the regurgitant orifice. It is also the first case series in the field of transcatheter tricuspid repair because it reports on 7 high-risk patients. The procedure was successful technically and safe in all cases. At 30 days, there were fewer signs of heart failure and better functional status. TR was reduced from severe to moderate.

LESSONS THAT CAN BE TAKEN FROM THIS VERY PRELIMINARY EXPERIENCE

1. Transcatheter tricuspid valve repair is feasible. Transvenous access to the tricuspid valve, through the jugular or femoral route, is much easier than that to the mitral valve and allows for placement of large devices. A transatrial approach is feasible, but requires a thoracotomy. In contrast, a transapical

*Editorials published in the *Journal of the American College of Cardiology* reflect the views of the authors and do not necessarily represent the views of *JACC* or the American College of Cardiology.

From the †Cardiology Department, Bichat Hospital, AP-HP; and the ‡University Paris Diderot, Paris, France. Dr. Vahanian is a consultant for Abbott Vascular and Edwards LifeSciences; and has received honoraria from Abbott Vascular, Edwards LifeSciences, and Valtech. Dr. Juliard has reported that he has no relationships relevant to the contents of this paper to disclose.

approach is not feasible on the right side. The Spacer device will probably be easier to position than the devices described earlier. Transcatheter valve replacement will be more challenging owing to the large size and the nonplanar nature of the tricuspid annulus, the absence of calcification on the annulus and the valves, and the risk of impeding atrioventricular conduction.

2. Echocardiography guidance will be integral as is the case in the mitral field even if imaging of the TR may be more difficult.
3. Safety is good, but needs to be assessed in a larger series. With the other devices, there is a potential risk of compromising the structures which are in the vicinity, such as the right coronary artery, which will require careful screening using computed tomography.
4. A short-term clinical improvement is observed despite the incomplete reduction in TR. This is a significant achievement for inoperable patients, in whom quality of life and reduction of rehospitalization and medical treatment are important.
5. The modest improvement in the degree of TR may have several explanations. First, the Spacer, as the other current devices, does not reproduce ring annuloplasty, which has been shown to be superior to stiches and Kay procedures (10). Second, patients treated in these first-in-man studies had irreversible enlargement of the tricuspid annulus and severe valve tethering. In such cases, repair is not expected to provide an effective, and certainly not a durable, reduction of TR and replacement is preferable. The series by Campello-Parada et al. (9) also illustrates that measuring TR after implantation of a Spacer will be challenging. In addition, measurement of severity of TR should be done by transthoracic echocardiography before and later after the procedure and not using transesophageal echocardiography during the procedure while the patient is under sedation because of the highly dynamic nature of TR.
6. The effect of RV function remains to be shown, which will be challenging. Magnetic resonance imaging is superior to echocardiography in this domain, but will be difficult to perform in the presence of defibrillators or pacemakers. The determination of the threshold for irreversible RV damage where isolated intervention on TR may be "futile" is largely unknown.
7. Durability remains to be investigated. Recurrence of TR will be a concern with all devices. In the particular case of the Spacer, we also need to know the long-term consequences of contact between the device and the leaflets, the risk of secondary dislocation, ventricular arrhythmias, and thrombosis.
8. The Heart Team approach will be essential to eliminate treating patients where comorbidities make any intervention futile. Similarly, durable effects of any tricuspid intervention cannot be expected if significant left-sided heart disease is left untreated. Finally, the Heart Team must select the most appropriate type of intervention. In high-risk patients, transcatheter therapy should be compared with medical therapy and perhaps also with minimally invasive tricuspid valve repair (11). Transcatheter repair may be expected to be durable and effective in well-selected secondary TR or primary TR without important leaflet damage but replacement may be preferable in other cases with secondary TR and most cases with primary TR.

In conclusion, there is a need for transcatheter tricuspid valve intervention. The current experience is preliminary and suggests feasibility, safety, and short-term clinical benefits. We should now follow what has been done successfully in the field of transcatheter aortic valve replacement, (i.e., carefully evaluate the results and refine the technology). The field of application of transcatheter tricuspid valve therapy will certainly be for high-risk or inoperable patients. In the future, if both tricuspid and mitral transcatheter interventions prove to be effective and durable, they could potentially be combined in patients at lower risk in the same way as in surgery. Finally, it may be expected that, in parallel to what is observed in the aortic and mitral fields, the introduction of tricuspid transcatheter repair will increase patient referral with the indirect consequence of increasing the number of operative interventions performed (12).

Thus, a lot of work is in front of us, but now the tricuspid valve will no longer be forgotten.

REPRINT REQUESTS AND CORRESPONDENCE: Dr. Alec Vahanian, Cardiology Department, Bichat Hospital, AP-HP, 46 rue Henri Huchard, 75018 Paris, France. E-mail: alec.vahanian@aphp.fr.

REFERENCES

1. Arsalan M, Walther T, Smith RL II, Grayburn PA. Tricuspid regurgitation diagnosis and treatment. Eur Heart J 2015 Sep 10 [E-pub ahead of print].

2. Taramasso M, Vanermen H, Maisano F, Guidotti A, La Canna G, Alfieri O. The growing

JACC VOL. 66, NO. 22, 2015
DECEMBER 8, 2015:2484–6

clinical importance of secondary tricuspid regurgitation. J Am Coll Cardiol 2012;59:703–10.

3. Vassileva CM, Shabosky J, Boley T, Markwell S, Hazelrigg S. Tricuspid valve surgery: the past 10 years from the Nationwide Inpatient Sample (NIS) database. J Thorac Cardiovasc Surg 2012;143:1043–9.

4. Lauten A, Doenst T, Hamadanchi A, Franz M, Figulla HR. Percutaneous bicaval valve implantation for transcatheter treatment of tricuspid regurgitation: clinical observations and 12-month follow-up. Circ Cardiovasc Interv 2014;7:268–72.

5. Laule M, Stangl V, Sanad W, Lembcke A, Baumann G, Stangl K. Percutaneous transfemoral management of severe secondary tricuspid regurgitation with Edwards Sapien XT bioprosthesis: first-in-man experience. J Am Coll Cardiol 2013;61:1929–31.

6. Schofer J, Bijuklic K, Tiburtius C, Hansen L, Groothuis A, Hahn RT. First-in-human transcatheter tricuspid valve repair in a patient with severely regurgitant tricuspid valve. J Am Coll Cardiol 2015;65:1190–5.

7. Kay JH, Maselli-Campagna G, Tsuji KK. Surgical treatment of tricuspid insufficiency. Ann Surg 1965;162:53–8.

8. Latib A, Agricola E, Pozzoli A, Denti P. First-in-man implantation of a trisuspid annular remodeling device for functional tricuspid regurgitation. J Am Coll Cardiol Intv 2015;8:e211–4.

9. Campelo-Parada F, Perlman G, Philippon F, et al. First-in-Man Experience of a Novel Transcatheter Repair System for Treating Severe Tricuspid Regurgitation. J Am Coll Cardiol 2015;66:2475–83.

10. Navia JL, Nowicki ER, Blackstone EH, et al. Surgical management of secondary tricuspid valve regurgitation: annulus, commissure, or leaflet procedure? J Thorac Cardiovasc Surg 2010;139:1473–82.e5.

11. Pfanmuler B, Misfeld M, Borger MA, et al. Isolated reoperative minimally invasive tricuspid valve operations. Ann Thorac Surg 2012;94:2005–10.

12. Mohr FW. Decade in review-valvular disease: current perspectives on treatment of valvular heart disease. Nat Rev Cardiol 2014;11:637–8.

KEY WORDS interventional cardiology, transcatheter valve, tricuspid regurgitation